



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0080]

Syngenta Seeds Inc.; Availability of Preliminary Finding of No Significant Impact and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Corn Genetically Engineered for Glyphosate and Glufosinate-Ammonium Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has reached a preliminary decision to extend our determination of nonregulated status of corn events Bayer/Genective S.A.VCO-Ø1981-5 (hereinafter Genective VCO-Ø1981-5 corn) and Pioneer's DP-ØØ4114-3 (hereinafter Pioneer 4114 corn) to Syngenta's corn event MZHG0JG in response to a request from Syngenta Seeds Inc. MZHG0JG corn has been genetically engineered for resistance to the herbicide glyphosate using the same mechanism of action as Genective VCO-Ø1981-5 and also to be resistant to the herbicide glufosinate using the same mechanism of action as Pioneer 4114. We are making available for public comment our preliminary finding of no significant impact for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
<http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0080>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0080, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The Syngenta Seeds Inc. extension request, our preliminary finding of no significant impact, our preliminary determination, and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0080> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents and any comments we received regarding our determination of nonregulated status of the antecedent organisms, Genective VCO-Ø1981-5 corn and Pioneer 4114 corn, can be found at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0046> and <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026>. Supporting documents may also be found on the APHIS Web site for MZHG0JG corn (the organism under evaluation) under APHIS Petition Number 15-124-01p, and the antecedent organisms Genective VCO-Ø1981-5 corn and Pioneer 4114 corn under APHIS Petition Numbers 11-342-01p and 11-244-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851-3885, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms (GE) and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

On September 25, 2013,¹ APHIS announced its determination of nonregulated status of corn (Zea mays) designated as event VCO-Ø1981-5 (hereinafter Genective VCO-Ø1981-5 corn),

¹ https://www.aphis.usda.gov/brs/aphisdocs/11_34201p_det.pdf.

which was genetically engineered for resistance to the herbicide glyphosate. On June 20, 2013,² APHIS announced its determination of nonregulated status of corn designated as event DP-ØØ4114-3 (hereinafter Pioneer 4114 corn), which was genetically engineered for resistance to the herbicide glufosinate-ammonium. APHIS has received a request for an extension of a determination of nonregulated status of Genective VCO-Ø1981-5 corn and Pioneer 4114 corn to corn designated as event MZHG0JG (APHIS Petition Number 15-124-01p) from Syngenta Seeds Inc. (Syngenta) of Research Triangle Park, NC. MZHG0JG corn expresses resistance to both glyphosate and glufosinate-ammonium. In its request, Syngenta stated that this corn is similar to the antecedent organisms, Genective VCO-Ø1981-5 corn and Pioneer 4114 corn and, based on the similarity to these antecedent organisms, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the extension request, MZHG0JG corn was developed through agrobacterium-mediated transformation to stably incorporate the transgenes mepsps-02 and pat-09 into the MZHG0JG corn genome. The gene mepsps-02 encodes the enzyme modified 5-enol pyruvylshikimate-3-phosphate synthase (mEPSPS), a variant of the native EPSPS enzyme from corn, which contains two amino acid substitutions that were introduced specifically to confer resistance to herbicides containing glyphosate. The gene pat-09 encodes the enzyme phosphinothricin acetyltransferase (PAT) derived from the soil bacterium Streptomyces viridochromogenes. PAT acetylates glufosinate-ammonium, thus inactivating it and conferring resistance to glufosinate-ammonium in herbicide products. The antecedent organisms, Genective VCO-Ø1981-5 corn and Pioneer 4114 corn, were similarly genetically engineered to produce proteins which catalyze the same reactions as do the proteins produced in MZHG0JG corn.

² https://www.aphis.usda.gov/brs/aphisdocs/11_24401p_det.pdf.

Based on the information in the request, we have concluded that MZHG0JG corn is similar to Genective VCO-Ø1981-5 corn and Pioneer 4114 corn. MZHG0JG corn is currently regulated under 7 CFR part 340.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS evaluates the plant pest risk of the article. In section 403 of the PPA, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS completed plant pest risk assessments (PPRA) on the antecedent organisms in which we concluded that Genective VCO-Ø1981-5 corn and Pioneer 4114 corn are unlikely to present plant pest risks. APHIS also prepared a plant pest risk similarity assessment (PPRSA) to compare MZHG0JG to the antecedents. As described in the PPRSA, the proteins expressed in MZHG0JG corn are similar to those expressed in Genective VCO-Ø1981-5 corn and Pioneer 4114 corn, and APHIS has concluded that the proteins expressed in Genective VCO-Ø1981-5 corn and Pioneer 4114 corn are unlikely to affect the plant pest risk of Genective VCO-Ø1981-5 corn and Pioneer 4114 corn. Furthermore, the Environmental Protection Agency reviewed the safety of the proteins expressed in MZHG0JG corn and concluded that adverse effects will not occur to nontarget organisms. Therefore, based on our PPRA for Genective VCO-Ø1981-5 corn and Pioneer 4114 corn and the similarity between Genective VCO-Ø1981-5 corn, Pioneer 4114 corn, and MZHG0JG corn as described in the PPRSA, APHIS has concluded that the proteins expressed in MZHG0JG corn are unlikely to pose a plant pest risk and that MZHG0JG corn is

unlikely to pose a different plant pest risk than Genective VCO-Ø1981-5 corn and Pioneer 4114 corn.

APHIS also prepared an environmental assessment (EA) for MZHG0JG corn based on our analysis of data submitted by Syngenta, a review of other scientific data, and field tests conducted under APHIS oversight. The EA was prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the determination of nonregulated status for MZHG0JG corn. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

In addition, APHIS has carefully examined the existing NEPA documentation completed for Genective VCO-Ø1981-5 corn and Pioneer 4114 corn and has concluded that Syngenta's request to extend a determination of nonregulated status to MZHG0JG corn encompasses the same scope of environmental analysis as Genective VCO-Ø1981-5 corn and Pioneer 4114 corn. Therefore, based on the similarity of MZHG0JG corn to Genective VCO-Ø1981-5 corn and Pioneer 4114 corn, APHIS has prepared a preliminary finding of no significant impact (FONSI) on MZHG0JG corn. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of MZHG0JG corn and it would continue to be a regulated article, or (2) make a determination of nonregulated status of MZHG0JG corn. APHIS' preferred alternative is to make a determination of nonregulated status of MZHG0JG corn.

APHIS has analyzed information submitted by Syngenta, references provided in the extension request, peer-reviewed publications, and information in the EAs of the antecedent organisms. APHIS has also analyzed information in the PPRA for the antecedent organisms, and other information. Based on APHIS' analysis of this information, the similarity of MZHG0JG corn to the antecedent organisms, our conclusion that the proteins expressed in MZHG0JG corn are unlikely to pose a plant pest risk, and our conclusion that MZHG0JG corn is unlikely to pose a different plant pest risk than Genective VCO-Ø1981-5 corn and Pioneer 4114 corn, APHIS has determined that MZHG0JG corn is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of Genective VCO-Ø1981-5 corn and Pioneer 4114 corn to MZHG0JG corn, whereby MZHG0JG corn would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of Genective VCO-Ø1981-5 corn and Pioneer 4114 corn to MZHG0JG corn.

APHIS will accept written comments on the preliminary FONSI regarding a determination of nonregulated status of MZHG0JG corn for a period of 30 days from the date this notice is published in the Federal Register. The preliminary FONSI, as well as the extension request, supporting documents, and our preliminary determination with appended PPRSA for MZHG0JG corn, are available for public review as indicated under ADDRESSES and FOR

FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments will be available for public review. After reviewing and evaluating the comments, if APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, our preliminary regulatory determination will become final and effective upon notification of the public through an announcement on our Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml. APHIS will also furnish a response to the petitioner regarding our final regulatory determination. No further Federal Register notice will be published announcing the final regulatory determination regarding MZHG0JG corn.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of October.

Michael C. Gregoire

Associate Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015-27296 Filed: 10/26/2015 08:45 am; Publication Date: 10/27/2015]